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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/444,711	11/24/1999	TIMOTHY J. YEATMAN	114205.400	9003

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/02/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/444,711

Applicant(s)

YEATMAN ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 29-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 28, 2002 has been entered.

2. Claims 29-38 are pending.

Claims 28 and 35 have been amended.

Claims 29-38 are examined on the merits. Claims 33 and 34 will be examined with group to the extent that the transgenic cell is a recombinant cell.

Specification

3. The disclosure is objected to because of the following informality: the drawings include Figure 4e, however the "Brief Description of the Drawings" section does not contain a figure legend/caption for the said figure. Correction is required.

Claim Objections

4. Claim 29 is objected to because of the following informality: the term "islolated" has been misspelled. Correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 29-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. In anticipation of the instant rejection Applicants argue that claim 29 has been amended "...to more distinctly define the claimed invention" and as amended this claim is "...directed to a polynucleotide wherein codon 531 serves as the termination or stop codon." This is found unpersuasive.

Claims 29, 35 and 37 are vague and indefinite for reciting "codon 531". It is not clear whether or not Applicants are referring to nucleotide 531 or amino acid residue 531. The Examiner has reviewed the entire specification for clarity. One citation referencing the codon language states on page 11, line 1 "...stop codon at residue 531,". This language implies that the codon is an amino acid residue. A codon is a set of three adjacent nucleotides that occur in mRNA. The recitation "531" seems to reference one nucleotide. It would seem that the three adjacent nucleotides encoding the stop codon is approximately between nucleotides 1590-1592. Applicants are

Art Unit: 1642

requested to clarify the phrase and designate the codon, which is to serve as the termination or stop codon. Accordingly, the metes and bounds are unclear.

b. The recitation "complement" in claim 30 is vague and indefinite. It is not clear whether or not the complement should include several nucleic acid base pairs or is a partial-length or a full-length complement. Accordingly, the metes and bounds of the claims cannot be determined.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 29-36 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,336,615 (August 9, 1994). In anticipation of the instant rejection

Art Unit: 1642

Applicants assert the "615 patent discloses genetically engineered endothelial cells" and "[i]n contradistinction, the present inventors have...discovered a novel mutation of Src 531...". Furthermore, Applicants argue that "'615 patent fails to provide ...an isolated polynucleotide encoding a mutant c-Src protein, wherein the polynucleotide has a *codon 531 which is a stop codon*." This is found unpersuasive.

Applicants' claims are directed to a polynucleotide, which is involved in malignant transformation and metastasis. This polynucleotide product is clearly disclosed in U.S. Patent #5,336,615 and accordingly anticipates the claimed invention. Moreover, arguments asserting that the fields of study between patent '615 and the instant application are not commensurate in scope.

U.S. Patent #5,336,615 discloses an isolated polynucleotide (Sequence 3 of '615 patent) encoding a mutant c-Src protein (Sequence 4 of '615 patent), wherein the polynucleotide has a codon 531 which is a stop codon comprising SEQ ID NO: 1 (see columns 21-28 and accompanying database sheets). The isolated polynucleotide was located downstream of a promoter (regulatory element), wherein transcription of the gene or part was initiated at the promoter contained within an expression vector/recombinant construct (see column 7, lines 51-55, and column 9, lines 1-5, 22-25). This oligonucleotide set forth in SEQ ID NO: 1 is a mutant c-Src gene that inherently is capable of recognizing and distinguishing a mutant c-Src gene having a codon 531 from a wild-type c-Src gene. Bovine calf aortic endothelial host cells were infected with a retroviral vector containing the disclosed polynucleotide/oligonucleotide of SEQ ID NO: 1 (see column 13, line 66-column 14, line 2). Also disclosed are

Art Unit: 1642

methods for producing, expressing and recovering the encoded protein (see column 11, lines 1-60 and Figure 2, bridging paragraph of columns 6 and 7).

9. Claims 29-36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number AAQ46688 and Accession number AAR39706 of WO 93/14193 A (July 22, 1993). These accession numbers of WO 93/14193 disclose a complement of SEQ ID NO: 1 and an isolated polynucleotide (Sequence 3 of WO document) encoding a mutant c-Src protein (Sequence 4 of WO document), wherein the polynucleotide has a codon 531 which is a stop codon comprising SEQ ID NO: 1 (see pages 69-72, 75-77 accompanying database sheets). The isolated polynucleotide was located downstream of a promoter (regulatory element), wherein transcription of the gene or part was initiated at the promoter contained within an expression vector/recombinant construct (see page 25, line 20-page 26, line 23; page 30, lines 14-25). This oligonucleotide set forth in SEQ ID NO: 1 is a mutant c-Src gene that inherently is capable of recognizing and distinguishing a mutant c-Src gene having a codon 531 from a wild-type c-Src gene. Bovine calf aortic endothelial host cells were infected with a retroviral vector containing the disclosed polynucleotide/oligonucleotide of SEQ ID NO: 1 (bridging paragraph of pages 44 and 45). Also disclosed are methods for producing, expressing and recovering the encoded protein (see pages 34-41).

Art Unit: 1642

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Applicants argue in anticipation of the instant rejection that the '615 patent is directed toward cardiovascular health, does not suggest truncation of the polynucleotide at codon 531 and the benefits of such a mutant protein in the field of cancer. These arguments are found unpersuasive for the reasons set forth in paragraph 8.

Claims 29-38 are rejected under 35 U.S.C. 103(a) as being unpatentable by U.S. Patent number 5,336,615 (August 9, 1994) and Accession numbers AAQ46688 and AAR39706 of WO 93/14193 A (July 22, 1993). The teachings of these references have been discussed in the 102 art rejections above. These references do not teach a diagnostic kit comprising the oligonucleotides of the patent and the said controls of claim 37.

Although the claims recite a kit, no positive recitation of the kit ingredients/elements distinguishes the claim over the references. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to form a kit. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in the art to place the recited oligonucleotides in a kit because it is a well-known convention in the art to place

Art Unit: 1642

the recited elements in a kit for the advantages of convenience and economy, as well as the recited elements would provide an efficient mode of diagnosis.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alana M. Harris, Ph.D.
July 1, 2002